Objections to the Drawings

The Examiner indicated that the formal drawings failed to comply with 37 CFR §1.84. New formal drawings are submitted herewith that are believed to address the objections.

Objections to the Specification

The Examiner objected to the specification on several grounds. First, the Examiner indicated that the specification should be amended to reflect the status of the parent applications. Applicants respectfully point out that in an Amendment filed January 26, 1998 the priority information was amended to reflect the conversion of serial number 08/585,005 to a provisional application (60/064,855). Applicants have herein amended the priority information to indicate that application serial number 08/667,197 is still pending.

The Examiner also objected to the title of the invention as not being descriptive. The title has been amended herein to more specifically describe the claimed invention. Similarly, the Examiner objected to the abstract of the disclosure as not adequately describing the claimed invention. The abstract has been amended herein such that it is descriptive of the claimed invention.

Claim Rejections Under 35 U.S.C §112, Second Paragraph

Claims 10-12 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner found that the metes and bounds of "biological characteristics" are unclear and indefinite.

Applicants respectfully disagree with the Examiner. However, solely to facilitate prosecution, claim 10 has been cancelled and claims 11 and 12 have been amended to adjust their dependencies. Thus, the rejection is no longer applicable.

Claim Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1-12, 22 and 25-29 are rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

First, the Examiner found that the antibodies claimed in claims 10-12 are essential to the claimed invention. The Examiner indicates that if the claimed antibodies were deposited with the ATCC under the terms of the Budapest Treaty, a statement should be made indicating that the antibodies have been deposited under the Budapest Treaty and that the antibodies will be irrevocably and with out restriction released to the public upon issuance of a patent.

Applicants respectfully submit that the specification at page 79, lines 4-13 indicates that hybridomas producing the claimed antibodies were deposited with the ATCC. In the Amendment filed January 26, 1998 the deposit numbers and dates were added to the specification. Further, copies of the ATCC deposit receipts were provided. At page 79, lines 3-7, it is explicitly stated that the hybridomas will be available for thirty years and that any restriction on their availability will be removed upon issuance of a patent.

Nevertheless, Applicants again state that the claimed antibodies have been deposited under the terms of the Budapest treaty and that the antibodies will be irrevocably and without restriction or condition released to the public upon the issuance of a patent. Further, the deposit will be maintained by the ATCC for a period of 30 years after the date of deposit, 5 years after the last request for a sample or for the enforceable life of any patent that issues from this application.

The Examiner also indicated that Applicant is required to amend the specification to include essential material that has been incorporated by reference. The specification has been amended to add the description from the cited Levin et al. reference that is relevant to testing molecules such as agonist antibodies for their ability to modulate body weight, fat-depot weight and food intake. The amendatory material consists of the same material incorporated by reference in the present application.

While the Levin et al. reference describes testing the effects of administering ob protein, one of skill in the art will recognize that the methods are readily applied to the testing of other proteins such as agonist antibodies, as indicated in the specification.

The Examiner rejected claims 1, 3-12, 22, and 25-29 under 35 U.S.C. §112, first paragraph, stating that the specification, while being enabling for a method for identifying an antibody which decreases body weight or fat-depot weight or food intake in an obese mouse does not provide enablement for such a method in any animal.

Applicants respectfully disagree and would like to point out that the claims are directed to a method for identifying agonist antibodies with a particular property and are not directed to a particular antibody. Thus, the inquiry is whether one of ordinary skill in the art could practice the claimed method without undue experimentation.

The specification teaches that agonist antibodies can be selected that decrease body weight or fat-depot weight or food intake in any obese mammal (page 69, lines 1-2). While the ob/ob mouse is provided as an exemplary obese mammal, the teachings of the specification are not so limited.

One of ordinary skill in the art will be able to "produce agonist antibodies which specifically bind to the extracellular domain of a receptor having a WSX motif comprising the extracellular domain sequence within SEQ ID NO: 2" without undue experimentation. Extensive methods for producing and identifying such antibodies are provided in the specification, such as in Examples 13 and 14.

Further one of skill in the art would be able to select agonist antibodies that have the ability to decrease body weight or fat-depot weight or food intake in an obese mammal. While such methods would be apparent to one of skill in the art, the specification refers to the teachings of Levin et al., now included explicitly, which provide methods for administering potentially active compounds to an obese animal and measuring a change in body weight, fat-depot weight or food intake. While Levin et al. refers to the administration of ob protein to ob/ob mice, it would be a trivial matter to one of skill in the art to modify the teachings to administer agonist antibodies to any obese mammal without undue experimentation.

The Examiner discusses the ob/ob mouse model at some length and states that "as no such genetic defect has been attributed to the obese condition in humans, one would not expect the same factor to be effective in humans..." The claimed method for identifying an agonist antibody is not dependent upon any particular genetic defects, but is related to the ability of

agonist antibodies to stimulate the WSX receptor. Thus, Applicants respectfully submit that the underlying reasons for obesity in the ob/ob mouse are not relevant to the enablement of the claimed method for identifying an agonist antibody. One of ordinary skill in the art would not have any reason to believe that the claimed method could not be performed with any obese animal.

As the claimed method could be performed by one of skill in the art without undue experimentation, Applicants respectfully request withdrawal of this rejection.

Claims 1-12, 22 and 25-29 are rejected under 35 U.S.C. §112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention. The Examiner states that this is a new matter rejection.

Applicants respectfully submit that the present claims are fully supported by the specification as filed and exemplary support is identified below. However, without acquiescing in the Examiner's position, claim 1 has been amended to more explicitly parallel the language of the specification.

First, methods for producing antibodies to the extracellular domain sequence within SEQ ID NO: are provided at pages 60-62 of the specification. Methods for selecting agonist antibodies are provided at page 67, line 3 through page 68, line 32.

More specific description of producing agonist antibodies which specifically bind to the extracellular domain of a receptor having a WSX motif comprising the extracellular domain sequence within SEQ ID NO: 2 can be found in Examples 13 and 14.

Support for the selection of agonist antibodies which induce a statistically significant decrease in body weight or fat-depot weight or food intake in an obese mammal can be found, for example, at page 69, lines 1-6.

Support for claim 2 can be found, for example, at page 69, lines 4-6, while support for claims 4 and 5 can be found at page 66, lines 20-25.

Support for claims 3 and 6 can be found in Example 13 and support for claims 7 and 8 can be found at page 68, lines 6-8. Support for claims 11, 12 and 22 can be found at page 66, line 26 through page 67, line 22.

Support for claims 25-29 can be found, for example, at page 18, lines 30-33, and at page 60, line 1 through page 64, line 13.

As the present claims are fully supported by the specification as file, Applicants request withdrawal of this rejection.

Claim Rejections Under 35 U.S.C. §102(e)

Claims 1-11 and 25-29 were rejected under 35 U.S.C. §102(e) as being anticipated by Tartaglia et al. (U.S. Patent No. 5,972,621). The Examiner states that Tartaglia et al. teach a method for identifying an antibody which decreases body weight in an animal by binding to the extracellular domain of ObR.

Applicants respectfully disagree. Tartaglia et al. fail to disclose a method for identifying antibodies that decrease body weight or fat depot weight or food intake in an obese animal by producing and testing agonist antibodies to WSX receptor extracellular domain as claimed. While Tartaglia et al. do list antibodies within their definition of agonists and antagonists of ObR, antibodies are one of a long list of possible agonists and antagonists (column 5, lines 47-56) and no method of identifying antibodies with the ability to decrease body weight or fat depot weight or food intake is provided.

The Examiner refers to a number of passages in the Tartaglia et al. reference. However, Applicants respectfully submit that none of these passages refers to a method for identifying antibodies with the ability to decrease body weight or fat-depot weight or food intake as claimed. For example, the Examiner refers to column 22-23 in particular. These columns discuss antibodies to ObR generally. For example, it is stated that antibodies to ObR can be used to detect ObR in a biological sample, utilized to evaluate the effect of compounds on expression levels of ObR, used in conjunction with gene therapy to evaluate the level of ObR expression in engineered cells and may be used for the inhibition of abnormal ObR activity (column 22, lines 25-42). Howeve, nowhere does Tartaglia teach or suggest a method for selecting agonist antibodies that decrease body weight or fat-depot weight or food intake as claimed.

As Tartaglia et al. does not teach or suggest the method of Claim 1, Applicants request that this rejection be withdrawn.

Conclusion

For the reasons presented above, Applicants respectfully submit that the present application is in condition for allowance and an early action to that effect is solicited. If any issues remain, the Examiner is invited to telephone Applicants' counsel at the number provided below in order to resolve such issues promptly.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 10, 2003

By: _____

Andrew N. Merickel
Registration No. P-53,317
Attorney of Record
Customer No. 20,995
(415) 954-4114

Version With Markings to Show Changes Made

In the Specification

The paragraph on page 1, lines 6-9 has been amended as follows:

This is a non-provisional application filed under 37 CFR §1.53(b) claiming priority under 35 U.S.C. §119(e) to provisional application serial no. 60/064,855 filed January 8, 1996 and claiming priority under 35 U.S.C. §120 to non-provisional application Serial No. 08/667,197 filed June 20, 1996, pending, which applications are incorporated herein by reference.

In the Claims

Claim 1 has been amended as follows:

1. (Four times amended) A method for identifying an antibody which decreases body weight or fat-depot weight or food intake in an obese animal, comprising the steps of

(a) producing agonist antibodies which specifically bind to the extracellular domain of a receptor having a WSX motif comprising the extracellular domain sequence within SEQ ID NO: 2, and

(b) selecting ~~testing~~ the agonist antibodies produced in step (a) which induce a statistically significant ~~for the ability to~~ decrease in body weight or fat-depot weight or food intake in an obese animal~~, and~~

~~(c) identifying an antibody that has at least one of the abilities tested in step (b)~~.

Claims 11 and 12 have been amended as follows:

11. (Twice Amended) The method of claim 1~~0~~ wherein said antibodies bind to the epitope bound by an antibody selected from the group consisting of 2D7 (ATCC Accession Number HB-12249), 1G4 (ATCC Accession Number HB-12243), 1E11 (ATCC Accession Number HB-12248) and 1C11 (ATCC Accession Number HB-12250).

12. (Twice Amended) The method of claim 1~~0~~ wherein said antibodies have complementarity determining region (CDR) residues from an antibody selected from the group consisting of 2D7 (ATCC Accession Number HB-12249), 1G4 (ATCC Accession Number HB-

12243), 1E11 (ATCC Accession Number HB-12248) and 1C11 (ATCC Accession Number HB-12250).

AMEND
W:\DOCS\ANM\ANM-4539.DOC
012003